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347959

The Dow Chemical Company
Midland, MI 48674



1803 Building

August 15, 2012

Document Processing Center (7407M)
(Attn: TSCA Section 8(e) Coordinator)
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460-0001



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Generic name: Amino Alcohol

Dear Sir/Madam:

The following information is being submitted by The Dow Chemical Company (Dow) pursuant to current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act. Dow has made no determination as to whether a significant risk of injury to health or the environment is actually presented by the findings.

The test substance was evaluated for skin corrosivity potential in an *in vitro* corrosion assay, EpiDerm (MatTek Corporation; Ashland, MA), utilizing cultured human epidermal cells. In this assay, the test substance was topically applied to a three-dimensional regenerated human epidermis tissue for two exposure periods, one for three minutes and another for one hour. Skin corrosion was expressed as the remaining cell viability after exposure to the test substance.

The tissue cell viability was measured using a standard cytotoxicity assay MTT (3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide) and reported as a percentage of the mean of negative control. Skin corrosion potential of the test substance was classified according to tissue viability following the two exposure periods. A test substance is considered corrosive if the mean viability is less than 50% at three minutes or $\geq 50\%$ at three minutes but less than 15% at one hour. Water served as a negative control and 8N potassium hydroxide was used as a positive control.

The mean tissue viability of the test substance dosing solutions following the three minute exposure period was 41.4% and following the one hour exposure period was 13.1%. Since the mean viability of the compound was less than 50% at three minutes, based on the EpiDerm prediction model for corrosion, the test substance was classified as corrosive.

Company Sanitized

SANITIZED

Questions may be addressed to the undersigned.

Sincerely,

Alicia M Fitzpatrick

Alicia M. Fitzpatrick

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Attachment

Attachment I

Substantiation Questions

1. Is your company asserting this confidential business information (CBI) claim on its own behalf? If the answer is no, please provide company name, address and telephone number of the entity asserting claim.

We are submitting this claim on behalf of ourselves.

2. For what period do you assert your claim(s) of confidentiality? If the claim is to extend until a certain event or point in time, please indicate that event or time period. Explain why such information should remain confidential until such point.

Confidentiality of the specific chemical identity should be maintained indefinitely. It is impossible to estimate the time span over which the specific chemical technology might be utilized. Knowledge of the chemical identity with the link to the company could enable competitors to identify the type of chemistry manufactured by The Dow Chemical Company.

3. Has the chemical substance information that you are claiming as confidential been disclosed to any other government agency, or to this Agency at any other time? Identify the Agency to which the information was disclosed and provide the date and circumstances of the same. Was the disclosure accompanied by a claim of confidentiality? If yes, attach a copy of said document reflecting the confidentiality agreement.

The chemical identity of the product has not been disclosed to the EPA.

4. Briefly describe any physical or procedural restrictions within your company relating to the use and storage of the information you are claiming CBI.

Information on the chemical identity and other data for this substance are held "COMPANY CONFIDENTIAL" which means it may not be disclosed outside the company without a Confidential Disclosure Agreement. Documents so classified are clearly stamped, may not be reproduced without permission, and are filed in security-locked cabinets.

5. If anyone outside your company has access to any information claimed CBI, are they restricted by confidentiality agreement(s)? If so, explain the content of the agreement(s).

The chemical identity of this substance has not been disclosed outside of the company. Disclosure of the confidential information is permitted through a Confidential Disclosure Agreement. The confidential information may only be disclosed to Regulatory personnel with a need to know.

6. Does the information claimed as confidential appear or is it referred in any of the following:
- (a) advertising or promotional material for the chemical substance or the resulting product;
 - (b) material safety data sheets or other similar materials (such as technical data sheets) for the substance or resulting product (include copies of this information as it appears when accompanying the substance and/or product at the time of transfer or sale);
 - (c) Professional or trade publications; or
 - (d) Any other media or publications available to the public or to your competitors.
- The chemical identity of the subject material has not been disclosed in any of the documents listed in the question with the possible exception of safety data sheets or forms used for submission for testing.

The identity of the chemical substance has been shared with others only under non-analysis/secretcy agreements.

7. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this substance? If so, please provide copies of such determinations.

No. To the best of our knowledge, the EPA, another federal agency, or court has not made any confidentiality determination regarding this substance.

8. Describe the substantial harmful effects that would result to your competitive position if the CBI information is made available to the public. In your answer, explain the casual relationship between disclosure and any resulting substantial harmful effects. Consider in your answer such constraints as capital and marketing cost, specialized technical expertise, or unusual processes and your competitors' access to your customers. Address each piece of information claimed as CBI separately.

We do assert that disclosure of the chemical identity would be likely to result in substantial harm to our competitive position. The exact chemical identity is trade secret known only to certain persons within The Dow Chemical Company or those bound by a confidentiality agreement. Public disclosure of the composition would enable competitors to avoid research and developments costs.

9. Has this substance been patented in the U.S. or elsewhere? Is a patent for the substance currently pending?

10. Is this substance/product commercially available and if so, for how long has it been available on the commercial market?

- (a) If on the commercial market, are you competitors aware that the substance is commercially available in the U.S.?

- (b) *If not already commercially available, describe what stage of research and development (R&D) the substance is in, and estimate how soon a market will be established.*
(c) *What is the substance used for and what type of product does it appear in?*

11. *Describe whether a competitor could employ reverse engineering to identically create the substance.*

R&D work was done on this molecule; however, at the current time there are no plans to sell or distribute this material for further evaluation in any application area.

12. *Do you assert that disclosure of this information you are claiming CBI would reveal:*

- (a) *confidential processes used in manufacturing the substance*
(b) *if a mixture, the actual portions of the substance in the mixture; or*
(c) *information unrelated to the effects of the substance on human health or the environment?*

Disclosure of this information would reveal information that would be useful to our competitors to understand the nature and progress of our research programs. Disclosure of the confidential chemical identity would not be related to the effects of the substance on the environment since the generic terminology used should be sufficient at this stage for public interest.

13. *Provide the Chemical Abstract Service Registry Number for the product, if known. Is your company applying for a CAS number now or in the future? If you have applied for a CAS number, include a copy of the contract with CAS.*

14. *Is the substance or any information claimed CBI the subject of FIFRA regulation or reporting? If so, explain.*

The substance claimed confidential is not subject to FIFRA regulation.